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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,555	07/30/2003	Kohei Miyazono	NY-LUD 5298.5-DIV-US	7477

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EXAMINER

HISSONG, BRUCE D

ART UNIT	PAPER NUMBER
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1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/630,555

Applicant(s)

MIYAZONO ET AL.

Examiner

Bruce D. Hissong, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

1. Applicant's response to the office action mailed on 7/12/2006, was received on 10/11/2006, and has been entered into the record.

2. Claims 32-33 are currently pending and are the subject this office action.

3. The text of those sections of Title 35, U.S.C. not included in this action can be found cited in full, in the previous office action mailed on 7/12/2006.

Specification

Objection to the specification, as set forth on p. 2 of the office action mailed on 7/12/2006, is withdrawn in response to Applicants' amendment to the specification to update the bibliographic information in the first paragraph.

Claim Objections

1. Objection to claim 32, regarding recitation of the phrase "active like", as set forth on p. 2 of the office action mailed on 7/12/2006, is withdrawn. The Examiner notes that the phrase "active like" was inadvertently included in the objection, and as pointed out by the Applicants, the phrase is not found in the claims.

2. The Examiner suggests the syntax of claim 32 can be improved by amending the phrase "activin like" to "activin-like".

Claim Rejections - 35 USC § 101

Claims 32-33 remain rejected under 35 USC § 101, regarding lack of a specific, substantial and credible asserted utility, or a well established utility, for the claimed antibody of the instant invention, as set forth on pages 2-5 of the prior office action mailed on 7/12/2006.

In the response received on 10/11/2006, the Applicants do not set forth any arguments to specifically refute the assertion that the claimed invention lacks utility under the current guidelines that were implemented on 1/5/2001. The Applicants point out that the language of the claims parallels the language of the parent case, which has issued as US 6,982,319, and the grandparent case, issued as US 6,331,621. It is noted that these patents cited by the Applicants as having utility were largely examined prior to 1/5/2001.

In response, the Examiner notes that these patents cited by the Applicants as having utility were largely examined prior to 1/5/2001. The '621 and '319 patents are drawn to a polypeptide encoded by the nucleic acid of SEQ ID NO: 9 ('621 patent), or an antibody that binds the polypeptide encoded by the nucleic acid of SEQ ID NO: 9 ('319 patent). The polypeptide encoded by SEQ ID NO: 9 of the '621 and '319 patents is disclosed to be ALK-5. The instant application is drawn to an antibody that binds to the polypeptide encoded by the nucleic acid of SEQ ID NO: 1, which is disclosed to be ALK-1. Therefore, although the ALK-5 protein, or antibodies that recognize ALK-5, have been deemed to have utility, the issuance of the '612 and '319 patents does not necessarily mean that ALK-1, or antibodies which bind ALK-1, also have utility. It is also noted that each application is considered on its own merits, and in the instant case, the disclosure of the instant specification fails to provide a specific, substantial, and credible asserted utility, or a well established utility, for the protein encoded by the nucleic acid sequence of SEQ ID NO: 1 (ALK-1), or antibodies which bind to the protein encoded by the nucleic acid sequence of SEQ ID NO: 1 (ALK-1). However, if Applicants present arguments or evidence showing that the ALK-1 protein, or antibodies which specifically bind ALK-1, have utility, the rejection will be reconsidered.

Claim Rejections - 35 USC § 112, first paragraph - enablement

1. Claims 32-33 remain rejected under 35 USC § 112, first paragraph, regarding lack of enablement because the claimed invention is not supported by a specific, substantial, and

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credible asserted utility, or a well established utility, as set forth on page 5 of the prior office action mailed on 7/12/2006, and as discussed in the above rejection under 35 U.S.C. 101.

2. Claims 32-33 remain rejected under 35 USC § 112, first paragraph, regarding lack of enablement for antibodies recognizing any possible polypeptide encoded by all possible nucleotides which can hybridize with the nucleic acid sequence of SEQ ID NO: 1, as set forth on pages 6-7 of the prior office action mailed on 7/12/2006.

In the response received on 10/11/2006, the Applicants argue that the language of the claims is enabling because the claim language mirrors that of the parent applications, which are now issued as US 6,331,621 and US 6,982,319.

This argument has been considered and is not persuasive. The claims are drawn to an isolated antibody that binds a protein having "activin like" kinase activity. In the absence of a clear definition of "activin like", the claims are drawn to any polypeptides encoded by any nucleic acid molecules capable of hybridizing to the nucleotide sequence of SEQ ID NO: 1. Also, it is noted that each application is considered on its own merits, and in the instant case, the Applicants have not presented any specific arguments or evidence that would specifically refute the assertion of lack of enablement, as set forth in the previous office action. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112, first paragraph – written description

Claims 32-33 remain rejected under 35 USC § 112, first paragraph, regarding lack of written description for polypeptides encoded by the nucleic acid of SEQ ID NO: 1, or antibodies recognizing polypeptides encoded by all possible nucleotides which can hybridize with the nucleic acid sequence of SEQ ID NO: 1, as set forth on pages 7-8 of the prior office action mailed on 7/12/2006.

In the response received on 10/11/2006, the Applicants argue that the language of the claims mirrors that of the parent applications, which are now issued as US 6,331,621 and US 6,982,319.

This argument has been considered and is not persuasive. The claims are drawn to an isolated antibody that binds a protein having "activin like" kinase activity. In the absence of a clear definition of "activin like", the genus of polypeptides encoded by any nucleic acid

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molecules capable of hybridizing to the nucleotide sequence of SEQ ID NO: 1 is not sufficiently limited by the claims or described in the specification. Also, it is noted that each application is considered on its own merits, and in the instant case, the Applicants have not presented any specific arguments or evidence that would specifically refute the assertion of lack of written description, as set forth in the previous office action. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112, second paragraph

Rejections maintained

1. Claims 32-33 remain rejected under 35 USC § 112, second paragraph, as being indefinite regarding a protein having “activin like” kinase activity, as set forth on page 8 of the prior office action mailed on 7/12/2006.

In the response received on 10/11/2006, the Applicants argue that the language of the claims mirrors that of the parent applications, which are now issued as US 6,331,621 and US 6,982,319.

This argument has been considered and is not persuasive. It is noted that each application is considered on its own merits, and in the instant case, the Applicants have not presented any specific arguments or evidence that would specifically define the metes and bounds of the phrase “activin like” kinase activity. Therefore, the rejection is maintained.

Rejections withdrawn

2. Rejection of claims 32-33 under 35 USC § 112, second paragraph, as being indefinite regarding the omission of specific wash conditions, as set forth on pages 8-9 of the prior office action mailed on 7/12/2006, is withdrawn in response to Applicant's amendments to claim 32 to recite specific wash conditions.

3. Rejection of claim 33 under 35 USC § 112, second paragraph, as being indefinite regarding the phrase “by amino acids.....”, as set forth on pages 8-9 of the prior office action mailed on 7/12/2006, is withdrawn in response to Applicant's amendments to claim 33 to recite an antibody which binds specifically to amino acids 145-166.....”.

Double Patenting

1. Rejection of claim 32 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of US 6,692,925, is withdrawn in response to Applicants arguments that the requirement for restriction in this case deemed immunoassays and antibodies to constitute separate, patentably distinct inventions.

2. Rejection of claim 32 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of US 6,982,319, is withdrawn in response to the filing of a terminal disclaimer over the '319 patent.

Conclusion

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hisson, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be

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reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
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ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER